UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KYLE GUTERBA, Derivatively On Behalf Of AXSOME THERAPEUTICS, INC., Plaintiff, vs. HERRIOT TABUTEAU, ROGER JEFFS, MARK COLEMAN, MARK SAAD, NICK PIZZIE, MARK JACOBSON, CEDRIC O'GORMAN and KEVIN LALIBERTE, Defendants, -and- AXSOME THERAPEUTICS, INC, Nominal Defendant.	Case No.: 23-737 **VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT** **JURY DEMANDED**

Plaintiff Kyle Guterba ("Plaintiff"), by and through his undersigned counsel, derivatively on behalf of Nominal Defendant Axsome Therapeutics, Inc. ("Axsome" or the "Company"), submits this Verified Shareholder Derivative Complaint (the "Complaint"). Plaintiff's allegations are based upon his personal knowledge as to himself and his own acts, and upon information and belief, developed from the investigation and analysis by Plaintiff's counsel, including a review of publicly available information, including filings by Axsome with the U.S. Securities and Exchange Commission ("SEC"), press releases, news reports, analyst reports, investor conference transcripts, publicly available filings in lawsuits, and matters of public record. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable

opportunity for discovery.

NATURE OF THE ACTTION

1. This is a shareholder derivative action brought on behalf of and for the benefit of the Company, against certain of its officers and/or directors named as defendants herein seeking to remedy Defendants (defined below) violations of Sections 10(b) and 21D of the Securities Exchange Act of 1934 (the "Exchange Act"), and their breaches of fiduciary duties and other wrongful conduct as alleged herein and that occurred from December 30, 2019 to the present (the "Relevant Period"). Defendants' actions have caused, and will continue to cause, substantial financial harm and other damages to the Company, including damages to its reputation and goodwill.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 because Plaintiff's claims raise a federal question under Section 10(b) of the Exchange Act, 15. U.S.C. § 78j(b), and Section 21D of the Exchange Act, 15 U.S.C. § 78u-4(f).

3. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

4. Venue is proper in this Court in accordance with 28 U.S.C. § 1391 because the Company is located at 22 Cortlandt Street, 16th Floor, New York, New York 10007.

PARTIES

Plaintiff

5. Plaintiff acquired the Company securities and will continue to hold his Axsome shares throughout the pendency of this action. Plaintiff will fairly and adequately represent the interests of the shareholders in enforcing the rights of the corporation.

Nominal Defendant

6. Nominal Defendant Axsome is a Delaware corporation with principal executive offices located at 22 Cortlandt Street, 16th Floor, New York, New York 10007.

Director Defendants

7. ***Defendant Herriot Tabuteau*** ("Tabuteau") has served as Chief Executive Officer ("CEO") and a director of the Company since its founding in January 2012. He is named as a defendant in the securities class action entitled *Gru v. Axsome Therapeutics, Inc., et al.*, Case 1:22-cv-03925 (S.D.N.Y.) (the "Securities Class Action").

8. ***Defendant Roger Jeffs*** ("Jeffs") has served as a director of the Company since December 2014.

9. ***Defendant Mark Coleman*** ("Coleman") has served as a director of the Company since December 2014.

10. ***Defendant Mark Saad*** ("Saad") has served as a director of the Company since December 2014.

11. Defendants Tabuteau, Jeffs, Coleman, and Saad are referred to hereinafter as the "Director Defendants."

Officer Defendants

12. ***Defendant Nick Pizzie*** ("Pizzie") has served as the Company's Chief Financial Officer ("CFO") since May 2018. He is named as a defendant in the Securities Class Action.

13. ***Defendant Mark Jacobson*** ("Jacobson") has served as the Company's Chief

Operating Officer since March 2020. Before then, he served as the Company's Senior Vice President of Operations at all relevant times. He is named as a defendant in the Securities Class Action.

14. ***Defendant Cedric O'Gorman*** ("O'Gorman") served as the Company's Senior Vice President of Clinical Development and Medical Affairs from September 2017 to September 2021. He is named as a defendant in the Securities Class Action.

15. ***Defendant Kevin Laliber***te ("Laliberte") served as the Company's Executive Vice President of Product Strategy from January 2021 to December 2021. He is named as a defendant in the Securities Class Action.

16. The Director Defendants and Defendants Pizzie, Jacobson, O'Gorman and Laliberte are referred to as the "Individual Defendants" or "Defendants".

THE COMPANY'S CORPORATE GOVERNANCE

17. As members of Board, the Director Defendants were held to the highest standards of honesty and integrity and charged with overseeing the Company's business practices and policies and assuring the integrity of its financial and business records.

18. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Axsome, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its investors that the Director Defendants were aware posed a risk of serious injury to the Company

DUTIES OF THE DIRECTOR DEFENDANTS

19. By reason of their positions as officers, directors, and/or fiduciaries of Axsome and because of their ability to control the business and corporate affairs of Axsome, the Director Defendants owed the Company and its shareholders the fiduciary obligations of trust, loyalty, good

faith and due care, and were and are required to use their utmost ability to control and manage Axsome in a fair, just, honest, and equitable manner. The Director Defendants were and are required to act in furtherance of the best interests of Axsome and its shareholders.

20. Each director and officer of the Company owes to Axsome and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, as well as the highest obligations of fair dealing. In addition, as officers and/or directors of a publicly held company, the Director Defendants had a duty to promptly disseminate accurate and truthful information regarding the Company's operations, finances, financial condition, and present and future business prospects so that the market price of the Company's stock would be based on truthful and accurate information.

21. The Director Defendants, because of their positions of control and authority as directors and/or officers of Axsome, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company. Because of their advisory, executive, managerial and directorial positions with Axsome, each of the Defendants had access to adverse non-public information about the financial condition, operations, sales and marketing practices, and improper representations of Axsome.

22. To discharge their duties, the officers and directors of Axsome were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Axsome were required to, among other things:

(a) Ensure that the Company complied with its legal obligations and

requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the SEC and the investing public;

(b) Conduct the affairs of the Company in an efficient, businesslike manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) Properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's business prospects, and ensuring that the Company maintained an adequate system of financial controls such that the Company's financial reporting would be true and accurate at all times;

(d) Remain informed as to how Axsome conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiries in connection therewith, take steps to correct such conditions or practices, and make such disclosures as necessary to comply with federal and state securities laws;

(e) Ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable federal, state and local laws, and rules and regulations; and

(f) Ensure that all decisions were the product of independent business judgment and not the result of outside influences or entrenchment motives.

23. Each Director Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the

Company, as well as in the use and preservation of its property and assets. The conduct of the Director Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of Axsome, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Director Defendants were aware or should have been aware posed a risk of serious injury to the Company.

24. The Director Defendants breached their duties of loyalty and good faith by causing the Company to misrepresent the information as detailed *infra*. The Director Defendants' subjected the Company to the costs of defending, and the potential liability from, the Securities Class Action. As a result, Axsome has expended, and will continue to expend, significant sums of money.

25. The Director Defendants' and the Individual Defendants' actions have irreparably damaged Axsome's corporate image and goodwill.

AUDIT COMMITTEE

26. The Audit Committee's Charters states in relevant part:

> The Audit Committee (the "Committee") of the Board of Directors (the "Board") of Axsome Therapeutics, Inc. (the "Company") is appointed by the Board to assist in fulfilling certain of the Board's oversight responsibilities. The Committee's purposes shall be:
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> A. To assist the Board in its oversight of (1) the accounting and financial reporting processes of the Company; (2) the risk management and internal controls of the Company; and (3) the Company's compliance with legal and regulatory requirements; and
>
> B. To interact directly with and evaluate the performance of the independent registered public accounting firm, including to determine whether to engage or dismiss the independent registered public accounting firm and to monitor its qualifications and independence.
>
> The role of the Committee is limited to oversight. The members of the Committee shall not be full-time employees of the Company and may or may not be accountants or auditors by profession or experts in the fields of accounting or

auditing and, in any event, do not serve in such capacity. It is not the duty of the Committee (a) to plan or conduct audits, (b) to independently verify management's representations, or (c) to determine that the Company's financial statements are complete and accurate, are prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), or fairly present the financial condition, results of operations, and cash flows of the Company in accordance with GAAP. These are the responsibilities of management and the independent registered public accounting firm.

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Duties and Responsibilities

A. Financial Reporting Process

1. The Committee shall review and discuss with management and the independent registered public accounting firm (i) the annual audited financial statements to be included in the Company's annual report on Form 10-K, the quarterly financial statements to be included in the Company's quarterly reports on Form 10-Q and the Company's disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations"; (ii) the matters required to be discussed pursuant to the Public Company Accounting Oversight Board ("PCAOB") Auditing Standard No. 16 "Communications with Audit Committees"; (iii) the form of audit opinion to be issued by the auditors on the financial statements; and (iv) any other financial disclosures to be included in SEC filings prior to their release. The Committee shall review major issues regarding accounting principles and financial statement presentations.

2. The Committee shall review and discuss with management and the independent registered public accounting firm (i) any major issues regarding accounting principles and financial statement presentation, including any significant changes in the Company's selection or application of accounting principles; (ii) any significant financial reporting issues and judgments made in connection with the preparation of the Company's financial statements, including the effects of alternative GAAP methods; (iii) the effect of regulatory and accounting initiatives; and (iv) off-balance sheet structures on the Company's financial statements.

3. The Committee shall recommend to the Board whether the audited financial statements should be included in the Company's annual report on Form 10-K.

4. The Committee shall review earnings press releases prior to their release, as well as the type of financial information and earnings guidance and the type of presentation to be provided to analysts and rating agencies. The Chairman of the Committee may represent the entire Committee for purposes of this review.

5. The Committee shall prepare the Committee report required by the rules of the SEC to be included in the Company's annual proxy statement or annual report on Form 10-K.

B. Risks and Control Environment

1. The Committee shall discuss periodically with management the Company's risk assessment and risk management policies and procedures. The Committee shall periodically discuss with management the Company's significant financial risk exposures and the actions management has taken to limit, monitor or control such exposures, including, but not limited to, reviewing, on an on-going basis, in conjunction with the Company's Compensation Committee, whether the Company's compensation programs create significant financial risk, and any action to monitor and control such risk.

2. The Committee shall review periodically the Company's Code of Ethics and Business Conduct, and shall have the authority to grant waivers of it to the Company's directors and executive officers.

3. The Committee shall oversee the Company's disclosure controls and procedures, including internal control over financial reporting, and, where applicable, shall oversee changes in internal control over financial reporting intended to address any significant deficiencies or material weaknesses in the design or operation of internal control and any fraud involving management or other employees that is reported to the Committee. In addition, the Committee shall review and discuss the annual report of the management's assessment of the effectiveness of the Company's internal control over financial reporting and the independent registered public accounting firm's report on, and attestation of, such management assessment, to the extent required by SEC rules.

4. The Committee shall review on an on-going basis, in conjunction with counsel, any legal and regulatory matters, including legal cases against, or regulatory investigations of, the Company, that could have a significant impact on the Company's financial statements.

C. Independent registered public accounting firm

1. The Committee shall be directly responsible for the appointment, compensation, retention, termination, if necessary, and oversight of the work of the independent registered public accounting firm (including resolution of any disagreements between Company management and the independent registered public accounting firm regarding financial reporting) for the purpose of preparing or issuing an audit report or related work or performing other audit, review or attestation services for the Company. The independent registered public accounting firm shall report directly to the Committee. The Company shall provide for appropriate funding, as determined by the Committee, for payment of compensation to the independent registered public accounting firm.

2. The Committee shall be directly responsible for the appointment, compensation, retention, termination, if necessary, and oversight of any other registered public accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company.

3. The Committee shall review and approve in advance the retention of the independent registered public accounting firm for the performance of all audit and non-audit services that are not prohibited and the fees for such services. Pre-approval of audit and non-audit services that are not prohibited may be pursuant to appropriate policies and procedures established by the Committee for the pre-approval of such services, including through delegation of authority to a member of the Committee. The Chairman of the Committee has been delegated authority to pre-approve audit and non-audit services that are not prohibited between meetings of the Committee. Any service that is approved pursuant to a delegation of authority to a member of the Committee must be reported to the full Committee at its next scheduled meeting.

4. The Committee shall, at least annually, consider the independence of the independent registered public accounting firm and obtain and review a written report by the independent registered public accounting firm describing (i) all relationships between the auditing firm and the Company, consistent with Independent Standards Board No. 1, (ii) the auditing firm's internal quality control procedures, and (iii) any issues raised by the most recent internal quality control review, peer review or PCAOB review or inspection of the auditing firm or by any other inquiry or investigation by governmental or professional authorities in the past five years regarding one or more audits carried out by the auditing firm and any steps taken to deal with any such issues, and shall actively engage in a dialogue with the independent registered public accounting firm about any relationships between the auditing firm and the Company or any services that the auditing firm provides or proposes to provide that may impact upon the objectivity and independence of the independent registered public accounting firm, and shall take or recommend that the Board take any appropriate action to oversee the independence of the independent registered public accounting firm.

5. The Committee shall review periodically any reports prepared by the independent registered public accounting firm and provided to the Committee relating to, among other things, the Company's critical accounting policies and practices; alternative treatments within generally accepted accounting principles for policies and practices relating to material items that have been discussed with management, including the ramifications of the use of such alternative disclosures and treatments and the treatment preferred by the independent registered public accounting firm; and any other material written communications between the independent registered public accounting firm and management, such as any management letter or schedule of unadjusted differences.

6. The Committee shall discuss with the independent registered public accounting firm any audit problems or difficulties, including any restrictions on the scope of the independent registered public accounting firm's activities or on access to requested information, management's response to same, and any other matters required to be brought to its attention under applicable auditing standards (e.g. Auditing Standard 16), including, without limitation, the auditors' evaluation of the quality of the Company's financial reporting, information relating to significant unusual transactions and the business rationale for such transactions and the auditors' evaluation of the Company's ability to continue as a going concern, and shall resolve any disagreements between the independent registered public accounting firm and management.

7. The Committee shall discuss with the independent registered public accounting firm the overall audit strategy and the scope, timing and plans for their audits, including the adequacy of staffing and staffing rotation.

8. The Committee shall annually review the qualifications, performance and objectivity of the Company's independent registered public accounting firm, including an evaluation of the lead audit partner, and to assure the regular rotation of the lead audit partner and consider regular rotation of the independent registered public accounting firm serving as the Company's independent auditors.

9. The Committee shall consider, and if determined to be appropriate, adopt a policy for the hiring by the Company of employees or former employees of the independent registered public accounting firm.

D. Other Matters

1. The Committee shall review, approve and oversee any transaction between the Company and any related person (as defined in Item 404 of Regulation S-K) and any other potential conflict of interest situations on an ongoing basis, in accordance with Company policies and procedures, and to develop policies and procedures for the Committee's approval of related party transactions.

2. The Committee shall establish procedures for (i) the receipt, retention, and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters, and (ii) the confidential, anonymous submission by Company employees of concerns regarding questionable accounting or auditing matters.

3. Review with the independent auditor and management the scope and results of any internal audit program, including responsibilities and staffing, and review the adequacy and performance of any internal audit functions of the Company.

4. The Committee shall provide oversight and review of the Company's asset management policies, including an annual review of the Company's investment

policies and performance for cash and short-term investments.

5. The Committee shall periodically review and assess the adequacy of the Company's insurance policies, including without limitation its director and officer insurance policy.

6. The Committee shall review and assess the adequacy of this Charter annually and recommend any proposed changes to the Board for its approval.

7. The Committee shall perform any other activities consistent with this Charter, the Company's Amended and Restated Certificate of Incorporation, the Company's Amended and Restated Bylaws, and governing law, as the Committee or the Board may deem necessary or appropriate.

8. The Committee shall conduct an annual evaluation of the performance of its duties under this charter and shall present the results of the evaluation to the Board. The Committee shall conduct this evaluation in such manner as it deems appropriate.

BACKGROUND

27. The Company is a biopharmaceutical company based in NYC, New York, engaging in the development of novel therapies for CNS conditions that have limited treatment options.

28. Defendant Tabuteau founded the Company in January 2012. The Company went public through an initial public offering on the NASDAQ stock exchange on November 19, 2015.

29. Two of the Company's five (5) core products from its CNS portfolio are its AXS-07 and AXS-05 treatments.

30. AXS-07 is a novel, oral, rapidly absorbed, multi-mechanistic, and investigational medicine for the acute treatment of migraine. AXS-05 is a treatment of major depressive disorder ("MDD").

31. AXS-05 and AXS-07 are the first two products that the Company submitted NDAs to the FDA. They were the Company's most immediate and direct chances to make a profit for its investors. The Company's first Annual Report that described AXS-05 and AXS-07 as the first two drugs in its "core CNS portfolio."

32. The Company sought FDA approval for AXS-07 and AXS-05 under the FDA's 505(b)(2) regulatory development pathway. Under that pathway, companies submit an NDA "that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference."

33. Market analysts consistently rated the Company positively based on the value that AXS-07 was expected to add to the Company according to the positive clinical trial results that the Company reported for AXS-07. For instance, on December 30, 2019, SunTrust Robinson Humphrey published a favorable report based on the Company's positive MOMENTUM trial data. In this report, the analyst stated that "we think AXS-07 is approvable based on data reported this morning." The primary two factors that contributed to the report's $100 price target for the Company stock were the values of AXS-05 and AXS-07. Cantor Fitzgerald similarly published a December 30, 2019 report in which it raised its 12-month price target for the Company from $104 per share to $125 per share based on the positive trial data for AXS-07.

34. Even as the Company researched and developed therapies, it explained in its Annual Reports that it did "not currently own or operate any manufacturing facilities for the clinical or commercial production of our drug candidates." It used "independent contract manufacturing organizations, or CMOs," to manufacture its drugs and supply its clinical trials. The Company also explained that it "conduct[ed] periodic quality audits of their facilities," concluding that Axsome's CMOs "***will be capable of providing sufficient quantities***" of product "***to meet our clinical trial supply needs***."

AXS-07

35. Defendants consistently caused the Company to inform stockholders that the

Company's Application for AXS-07 was proceeding smoothly along a rapid timeline. The Company promoted positive test results and feedback from the FDA that Defendants represented as supporting the AXS-07 Application. However, Defendants caused the Company to delay its submission of the NDA. Then, after submitting the NDA, the Company announced that the FDA found CMC problems with the Application. This negative feedback would lead to substantial delays in the Company being able to resubmit an NDA for AXS-07.

36. The Company describes AXS-07 as "a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine under development for the acute treatment of migraine." AXS-07 consists of what the Company calls "MoSEIC™, or Molecular Solubility Enhanced Inclusion Complex," including meloxicam and rizatriptan. The Company describes this as a "combination drug," which is "a single drug product that consists of two or more active ingredients, with each component making a contribution to the claimed effect of the drug."

37. "Meloxicam is a long-acting nonsteroidal anti-inflammatory drug, or NSAID" with "potent pain-relieving effects." AXS-07 uses the Company's proprietary MoSEIC™ technology to "substantially increase" the speed at which meloxicam takes effect "while potentially maintaining durability of action."[1] Rizatriptan is included in AXS-07 because it "may reduce the release of inflammatory mediators from trigeminal nerves" and "is approved as a single agent for the acute treatment of migraine."

[1] The Company also explains that "AXS-07 consists of MoSEIC™, or Molecular Solubility Enhanced Inclusion Complex, meloxicam and rizatriptan. Meloxicam is a long-acting nonsteroidal anti-inflammatory drug, or NSAID, with COX-2, an enzyme involved in inflammation and pain pathways, preferential inhibition and potent pain-relieving effects. However, standard meloxicam has an extended time to maximum plasma concentration, or Tmax, which delays its onset of action. AXS-07 utilizes our proprietary MoSEIC™ technology to substantially increase the solubility and speed the absorption of meloxicam while potentially maintaining durability of action. Meloxicam is a new molecular entity for migraine enabled by our MoSEIC™ technology."

38. In February 2019, the Company reached an agreement with the FDA for the Company's planned MOMENTUM (Maximizing Outcomes in Treating Acute Migraine) Phase 3 trial of AXS-07. The Company represented that the FDA agreed that the protocol for the MOMENTUM trial (*e.g.*, entry criteria, dose selection, endpoints) "adequately address objectives that, if met, will support filing of an NDA of AXS-07 for the indication of acute treatment of migraine in adults with or without aura."[2]

39. In August 2020, the Company announced a successful Pre-NDA meeting with the FDA for AXS-07 for the acute treatment of migraine.

40. The Company initiated the MOMENTUM study in March 2019. On December 30, 2019, the Company announced that AXS-07 had met its two regulatory co-primary endpoints in the MOMENTUM study. In particular, the Company announced that it "achieved co-primary and key secondary endpoints and significantly improved migraine pain, freedom from most bothersome symptoms, and sustained pain freedom, in the MOMENTUM study."

41. The Company also told its stockholders that the results from the MOMENTUM study supported the filing of an NDA for AXS-07 for "the acute treatment of migraine"; that "[b]ased on FDA feedback, Axsome believes that MOMENTUM will be the only efficacy trial required to support an NDA filing for AXS-07 for the acute treatment of migraine"; and that "Axsome plans to file the NDA in the second half of 2020."

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[2] A Phase 3 clinical trial is the final stage of study before a new drug is submitted to the FDA for approval through an NDA. Phase 1 typically involves a very small number of participants (usually 100 or fewer) and tests a drug's overall safety and dosage. Phase 2 typically tests the drug on a larger group of people (up to a few hundred) to assess its efficacy and further assess its safety. A drug that passes Phase 1 and Phase 2 can then be subject to Phase 3 trials. Phase 3 trials are the most rigorous, as they typically test the drug on a larger group of people in a more controlled manner, and possibly for longer duration, to further assess the drug's efficacy in comparison to current treatment options and safety.

42. Defendant Tabuteau stated in the Company's press release that day that "[w]ith these positive [Phase 3] results, we look forward to filing an NDA for AXS-07 in the acute treatment of migraine in 2020."

43. The Company told its stockholders that AXS-07 was proceeding along this timeline and would be a major milestone in the Company reaching the commercial stage of its key products.

44. The Company also conducted a second Phase 3 trial on AXS-07 called INTERCEPT. The Company told its stockholders this study would bolster the strength of its NDA even further. The Company initiated the INTERCEPT study in October 2019.

45. In April 2020, the Company announced that AXS-07 achieved the co-primary endpoints in the INTERCEPT study. The Company then proceeded to promote both the MOMENTUM and INTERCEPT studies as supporting the Company's NDA for AXS-07.

46. In addition to what the Company described as its positive results from MOMENTUM and INTERCEPT, the Company conducted a "Phase 3, open-label, long-term safety extension study of AXS-07 . . . to further support the NDA filing," as the Company explained in a May 8, 2020 press release. The Company called this the MOVEMENT (Multimechanistic Treatment Overtime of Migraine Symptoms) trial and stated that it would support the planned NDA for AXS-07.

47. For instance, on August 10, 2020, the Company stated in connection with its results for the second quarter of 2020, that "***we remain on track to submit the NDA for AXS-07 for the acute treatment of migraine in the fourth quarter***. To that end, we have completed enrollment in the Phase 3 open-label safety extension trial of AXS-07 in migraine, which we call the MOVEMENT study to support the planned NDA filing. As we move towards the filing of our NDA[] in the fourth quarter . . . for AXS-07, our commercial team is focused on launch-readiness

activities to ensure successful commercial execution."

48. Despite consistently assuring its stockholders that AXS-07 was on track to have its NDA submitted in 2020 based on its successful results from its MOMENTUM, INTERCEPT, and MOVEMENT trials, the Company surprised investors by reporting, on November 5, 2020 (in connection with the Company's third quarter 2020 results) that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

49. The Company portrayed this issue arising from information related to the manufacturing of AXS-07 as a minor delay that could be solved by submitting more information to the FDA. The Company did not give any indication that there were actual problems with the manufacturing process for AXS-07 that might result in the FDA's rejection of its NDA. Rather, Defendants continued to mislead investors by assuring them that the "inclusion of supplemental manufacturing information" would address any concerns and "ensure a robust submission package."

50. For instance, even after the Company's November 5, 2020 announcement of a delay in the AXS-07 NDA, the Company stated in its Form 10-Q for the first quarter of 2021, filed with the SEC on May 10, 2021, that "[w]e plan to submit an NDA for AXS-07 for the acute treatment of migraine supported by the positive results from the MOMENTUM and INTERCEPT trials. An open-label, long-term, safety study of AXS-07 in patients with migraine known as the MOVEMENT trial has also been completed. In the MOVEMENT trial, administration of AXS-07 resulted in rapid, and substantial relief of migraine pain and associated symptoms and was well tolerated with long term dosing."

51. The Company did not end up submitting its NDA for AXS-07 until June 2021—months after its already-delayed timeline of the first quarter of 2021 that the Company announced on November 5, 2020.

52. On September 14, 2021, the Company announced that the FDA had "accepted for filing the Company's New Drug Application (NDA) for AXS-07 for the acute treatment of migraine and has set a Prescription Drug User Fee Act (PDUFA) target action date of April 30, 2022 for the NDA."[3]

53. Defendant Tabuteau stated in this press release that "[t]he FDA's acceptance of the NDA for AXS-07 is an important milestone for Axsome as it brings us closer to potentially making this multi-mechanistic treatment available to migraine patients in need." Defendants added that "[w]e look forward to continued interactions with the FDA during the review process" and that the NDA for AXS-07 "is supported by results from two Phase 3 randomized, double-blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials."

The FDA's Negative Feedback Regarding AXS-07

54. On April 25, 2022, the Company announced that on April 22, 2022 it was informed by the "FDA that chemistry, manufacturing, and controls ('CMC') issues identified during the FDA's review of the Company's New Drug Application ('NDA') for its AXS-07 product candidate for the acute treatment of migraine are unresolved. Based upon the time remaining in the NDA review cycle, the Company expects to receive a Complete Response Letter ["CRL"] with respect to this NDA on or about the Prescription Drug User Fee Act target action date of April 30,

[3] The PDUFA was first passed in 1992. It requires that companies pay a fee when they submit NDAs in order to enable the FDA to timely review NDAs. The standard timeline for the FDA to complete a review under the PDUFA is 10 months and is 6 months for priority reviews.

2022."

55. On this news, the Company's stock price fell $8.60 per share, or 21.99%, to close at $30.50 per share on April 25, 2022.

56. On April 25, 2022, William Blair published a report that described this news as "obviously disappointing," noting that the stock is down 24% premarket and that this would cause a substantial delay in the approval of AXS-07.

57. The Company's April 25, 2022, announcement that the FDA found CMC issues with AXS-07 indicates that the FDA had previously communicated its concerns to the Company. This announcement notes that the issues that the FDA had identified were "unresolved" as of April 22, 2022. The FDA had given the Company a chance to resolve these issues, but the Company failed to address them. If the FDA had not told the Company about these problems previously, the FDA would have simply stated that it would be issuing a CRL because of issues that it identified with the NDA. Instead, the resolution period that the FDA referenced indicates that it had given the Company a chance to resolve these issues, but the Company failed to address these defects. Despite the FDA previously informing the Company about these issues with the AXS-07 NDA, this was the first time that the Company publicly disclosed that the FDA had any concerns whatsoever with the Application.

58. Moreover, regardless of whether the FDA had communicated these CMC issues to the Company before April 22, 2022, they existed—and posed an extreme risk to the pending NDA—much earlier in the development process for AXS-07.

59. The Company then announced on May 2, 2022, that it received the Response from the FDA for the AXS-07 NDA. The Company stated that "[t]he CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any

new clinical trials to support the approval of AXS-07. The principal reasons given in the CRL relate to [CMC] considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. Axsome believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA." The Company could not give any indication at that point in time as to when it might be able to resubmit an NDA for AXS-07.

The Company's Development of AXS-07 Was Riddled with CMC Issues

60. Part of an NDA includes completing a section on the drug's chemistry, manufacturing and controls (CMC). This relates to the company's process for manufacturing the product. It also confirms that the product that is being tested in a limited capacity in the approval process is consistent with the product that will be manufactured and sold commercially, in much larger quantities, following FDA approval. CMC requirements ensure that the manufacturing process produces a safe and effective drug that is consistent with the drug that was used in clinical trials and is the subject of an NDA.

61. For instance, a contract research organization (CRO) that provides testing and research support services in the pharmaceutical industry explains that "[a]fter clinical trials the scale up process must ensure that the larger batches of product are the same and meet the same specifications as the drug tested in the clinical trials. After the manufacturing process is qualified, lot release and in process testing will continue to take place."[4]

62. CMC issues are a crucial part of the FDA approval process because even if a drug is safe and effective in theory, it must also be so in the real world. A drug should not be sold to the public if it is not being manufactured in the way it is supposed to be.

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4 https://pacificbiolabs.com/cmc-chemistry-manufacturing-and-controls.

63. The Company's development of AXS-07 was plagued by CMC issues. After the FDA issued the CRL for the AXS-07 NDA, Defendant Tabuteau stated on the Company's May 2, 2022 earnings call for the first quarter of 2022 that "[t]he principal reason given in the CRL relate to chemistry, manufacturing and controls or CMC considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. We believe that all the issues raised in the CRL are addressable." While Tabuteau continued to promote the efficacy and safety aspects of its clinical trials for AXS-07, he was not able to provide any update as to its submission of a new NDA other than to say that "[w]e intend to provide potential timing for a resubmission following consultation with the FDA."

64. On a May 2, 2022 call, in a response to a request for more information about the CRL for AXS-07, Defendant Jacobson explained that "as we mentioned, the questions and the request for additional information, they principally relate to drug product and the manufacturing process. So just a reminder that AXS-07 incorporates our MoSEIC technology, with a novel technology that Axsome developed." He concluded, "[a]nd so that does increase the complexity of the manufacturing process, the MoSEIC technology. And so we understand the basis for many of the questions, and we do believe they're addressable."

65. Defendant Tabuteau noted, conciliatorily—now that the public was aware of CMC problems with AXS-07—that "we fully understand the reasons why the [FDA] would want to make sure that any new technology, any new manufacturing process is fully vetted."

66. The most that Defendant Tabuteau could say as to timing was that "[w]hat we're looking to do is to meet with the FDA as expeditiously as possible. That's a Type A meeting. We want to make sure that we get our ducks in a row prior to requesting that meeting and getting a date. Once we have that meeting and we get feedback from the agency. In other words, we confirm

exactly what it is that should go into the resubmission that we can have success, then we'll be in a position to provide you with updated guidance on timing." He also noted "that we do expect that once we resubmit that the resubmission would likely be treated as a Class II resubmission, leading to a six-month review."

67. In addition, in response to a question about whether the CRL addressed any other issues beyond CMC questions, Defendant Tabuteau stated that it dealt "principally with all CMC" but "there was one item related to non-clinical, which was just our quest for additional information, which we believe we can provide. So for us, the real focus is this is a stand [stet] focus is CMC."

68. While Defendants have been vague in their public disclosures as to the nature of the CMC problems that the FDA identified with AXS-07, a former employee, who was a Senior Clinical Trial Manager at Axsome from July 2019 to February 2022 (Confidential Witness 1 ("CW 1"))[5], provided details of what the issues were.

69. CW 1 reported to the Executive Director of Clinical Research (Amanda Jones), the Director of Clinical Operations (Cheryl Askew), and the Senior Director of Clinical Operations (Caroline Streicher) at various points during CW 1's tenure at the Company. CW 1 was based in the Company's NYC office.

70. In early 2021, CW 1 was tasked to start managing a new study to provide additional data for AXS-07 that was scheduled to begin at the end of April 2021. The purpose of this study was to support the marketing of AXS-07 with additional published data. The study initially got delayed until August 2021 and then until November 2021.

71. The reason for this delay was that the Company did not have a sufficient supply of

[5] The confidential witnesses are taken from the Securities Class Action and are based on information and belief.

AXS-07 for the study. The supply of AXS-07 that the Company had available was nearing its expiration date, so the Company needed to produce more for the study.

72. According to CW 1, around August 2021, Fang Liu, the Company's Senior Director of Supply Chain for AXS-07, told CW 1 directly that one of the contract manufacturing organizations that the Company contracted with to produce AXS-07 was having equipment problems and was therefore unable to manufacture the drug.

73. As the months passed, the Company continued to wait for the necessary supply of AXS-07. When it continued to not receive the drugs, the Company delayed the study again, this time planning to conduct it in early 2022. At that point, Liu told CW 1 again that the manufacturer was ***still*** having equipment problems that it was not able to resolve. These problems therefore persisted at least from April 2021 through when CW 1 left the Company in February 2022.

74. According to CW 1, the Company used one vendor to supply meloxicam and another vendor to supply rizatriptan, which are the two active ingredients in AXS-07. The Company then used a third vendor to combine the two products to make AXS-07. It was this third vendor that was having problems with the equipment used to combine the two drugs. Liu told CW 1 that the Company was waiting for the vendor to fix the equipment and was not trying to find a new vendor to manufacture the drug.

75. CW 1 stated that the CMC issues that the FDA identified in its CRL for AXS-07 involved this contract manufacturing organization's equipment problem.

76. Furthermore, CW 1 stated that the Company's executive management would have known about the CMO's equipment problems.

77. In addition to being attested to by CW 1, this knowledge of senior management comports with the manufacturing problems that CW 1 described. CW 1 observed that the

Company was not able to produce one of its core drug candidates, which was one of only two drugs for which the Company was in the process of submitting NDAs. This delay went on for an extended period of time and caused a trial that the Company was working on to be delayed indefinitely. Axsome's senior management would have known of this delay that made the Company completely unable to manufacture, or conduct studies on, one of its main products for an extended period of time.

78. Moreover, the timing of this delay in the Company's ability to manufacture AXS-07 coincided with the FDA's review of the NDA for the drug. The Company delayed the submission of the NDA from the end of 2020 to the first quarter of 2021, and then delayed it again, to the second quarter of 2021. This timing aligns with the delay in the ability of the Company's CMO to manufacture AXS-07 for a study that was initially scheduled to begin in April 2021, but then ended up being delayed indefinitely over the course of the FDA's review of the Application.

79. On the Company's earnings call for the fourth quarter of 2020, held on March 1, 2021, an analyst asked why the AXS-07 NDA submission had been pushed back to the second quarter of 2021. Defendant Tabuteau responded that "[w]ith regard [AXS-]07 and the NDA filing the team remains on track to complete the filing by the end of the quarter. However, we are waiting on one vendor report which will slip into very beginning of the second quarter and that's the reason[.]" While Defendant Tabuteau did not disclose any information about the vendor's actual problems with manufacturing AXS-07 or give investors any indication that such problems existed, this statement about the timing of the vendor's report corroborates CW 1's description of when the vendor's manufacturing problems arose.

80. This manufacturing problem with AXS-07 was particularly material because the CMO's inability to manufacture enough of the drug even for limited clinical trials demonstrates

the Company's inability to produce AXS-07 on the timeline and scale necessary for commercializing it.

81. Moreover, the manufacturing problem with AXS-07 stemmed from the particularly complex nature of the drug, which required a third vendor focused specifically on combining the component parts of AXS-07 that were themselves obtained from two separate vendors.

82. All of these factors show that the Company's extended problems with manufacturing AXS-07 were not just run-of-the mill equipment problems, but rather, were severe obstacles that prevented the Company from being able to successfully manufacture AXS-07 for commercial purposes.

83. Defendants' disclosure of the delay in submitting the AXS-07 Application, followed by the CRL, confirms, in material part, the information from CW 1. For instance, the Company announced on November 5, 2020, that it was delaying its submission of its NDA for AXS07 "to allow for inclusion of supplemental manufacturing information to ensure a robust submission package." On the Company's earnings call that day, an analyst asked for Defendants to "provide more specifics on what manufacturing data related to the MoSEIC platform will be added for AXS-07." Defendant Tabuteau gave the following response:

> Great. So with regards to the additional manufacturing information, this is a standard information when you manufacture additional batches. So we continue to manufacture additional batches of drugs. And while we already have very long-term stability data on other batches, we think that because of the unique nature of the delivery technology, this can only help to make the submission robust and assure that there are no hiccups during review.

84. This explanation—while not disclosing the truth because Defendant Tabuteau falsely represented that the Company was able to continue manufacturing AXS-07—indicates that the Company was continuing to work on the "long-term stability" of the manufacturing capacity it needed to commercialize AXS-07. This information that Defendant Tabuteau gave on the

November 5, 2020 earnings call also did not disclose the truth because Defendant Tabuteau described the additional information that the Company needed as "standard" and not concerning. But his responses show that the problem that CW 1 observed with the Company's CMO for AXS-07 being able to manufacture the product is consistent with the topics that Tabuteau discussed—even if he did so in a coded way so as not to reveal the problems that the Company's vendor was having manufacturing AXS-07.

85. In addition, Defendants caused the Company to disclose on May 2, 2022, that the CRL related "to the drug product and manufacturing process."

86. Moreover, as Defendants caused the Company to disclose on May 2, 2022, the CRL was not even focused exclusively on CMC issues because those were only the "principal reasons" that formed the basis for the CRL.

87. In addition to the specific issue related to the manufacturing of AXS-07, CW 1's observations reflect a more systemic problem with the Company's quality controls. CW 1 commented that the Company's executive leadership appeared to prioritize profit over patients and that they "cut corners." In addition, the Company seemed to always be in a rush to meet milestones.

88. And, as described further below, CW 1 observed a separate issue in a study for AXS-05 caused by a poorly written testing protocol that allowed unqualified patients to participate in the relevant clinical study and resulted in the Company receiving a Form 483 from the FDA for its failure to exclude unqualified patients from participating in the study.

AXS-05

89. Defendants should have been on heightened notice for CMC issues with AXS-07 because the Company had just experienced a similar issue with its other main product, AXS-05

for the treatment of MDDs. Stockholders also expected that the Company would not make the same mistake twice in a row and were shocked by the Company's repeated CMC failures on two consecutive NDAs in short succession.

90. For instance, in an April 25, 2022 report, Cantor Fitzgerald lowered its price target for the Company as a result of the news about the FDA's denial of the AXS-07 NDA, calling it "déjà vu," explaining that "[t]he Company ran into regulatory issues for its NDA of '05 for MDD as the agency had identified two deficiencies related to analytical methods in the CMC which needed to be addressed prior to the FDA taking action on the NDA. Although we had previously indicated that we believe these CMC issues have been resolved, our conviction that that is the case is now decreased as ***CMC deficiencies appear to be a persistent issue plaguing the company***."

91. Cowen also advised stockholders to "[r]ecall that the company had previously indicated that the FDA expected to complete the required inspection of the AXS-07 contract manufacturing facility prior to the April 30 PDUFA date and the company had not communicated any other delays with the review prior to today, thus the update comes as a disappointment. Additionally, given the history of the AXS-05 review in MDD, investors are likely not to take kindly to any uncertaint[y] between the company and the FDA."

92. Also, on April 25, 2022, Morgan Stanley published a note titled "Surprise Setback for AXS-07 in Migraine Presents Additional Pipeline Uncertainty." The note explained that "the surprise setback for AXS-07 is likely to increase investor uncertainty regarding prospects for the AXS-05 NDA - particularly given the hurdle faced by both applications are CMC related." As a result of this news, Morgan Stanley stated that "[w]e would expect significant pressure on AXSM following the update on AXS-07. We continue to remain on the sidelines with an EW rating and note that our PT for AXSM is currently under review." It also described one of the primary risks

that the Company faced as being an "FDA rejection of Axsome's NDA for AXS-07 in migraine."

93. Also, the SMBC Group commented in a note that day entitled "More Storm Clouds Gathering with Pending Rejection for AXS-07 in Migraine," that the Company's stock suffered a 22% drop that day "on the negative news" and that "[w]e view the stock move as appropriate." This news would result in a "sizable delay" for the approval and launch of AXS-07, which led SMBC Group to lower its price target for the Company from $45 per share to $29 per share. SMBC Group also commented that given the Company's prior problems with AXS-05, regardless of whether the CMC problem with AXS-07 was "related to some of the problems that have been encountered previously with" AXS-05, "***troubles in manufacturing seem to be a recurring theme with AXSM's drug candidates***."

94. The Company developed AXS-05 for the treatment of MDD, among other conditions. The Company states that it "believe[s] there is a substantial need for new, more effective treatments for this large, underserved patient population." It describes AXS-05 as "a novel, oral, investigational NMDA receptor antagonist with multimodal activity."[6]

95. In July 2020, the Company announced a positive pre-NDA meeting with the FDA regarding the Company's planned NDA submission of AXS-05 for the treatment of MDD. The Company submitted the NDA for AXS-05 for MDD in early 2021.[7]

96. On April 26, 2021, the Company announced that the FDA accepted the NDA for AXS-05 for MDD for priority review. This means that the FDA accelerated the review time from the standard 10 months to 6 months, making the Prescription Drug User Fee Act target action date August 22, 2021. The Company stated that "[t]he NDA is supported by results from two

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6 An NMDA receptor is a type of neurological receptor.

7 The Company announced on March 1, 2021, that it submitted the NDA earlier that year, but did not provide the specific date.

randomized, double-blind, controlled trials of AXS-05 in patients with a confirmed diagnosis of moderate to severe MDD."

97. Then, the Company shocked stockholders by announcing before the market opened on August 9, 2021—less than two weeks before the August 22, 2021, PDUFA date for AXS-05—that the FDA found "deficiencies" with the NDA. The Company stated in a press release that day that "[a]s part of the ongoing review of our NDA for AXS-05, the FDA recently notified us that they have identified deficiencies that preclude labeling discussions at this time." The Company added, "[w]e are attempting to learn the nature of these deficiencies with the goal of addressing them, however, this development may lead to a delay in the potential approval of AXS-05."

98. The August 9, 2021, press release continued, explaining that "[o]n July 30, 2021, the Company received a letter from the FDA stating that it has identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time." With respect to FDA approval, the Company concluded, "[t]he letter stated further that the notification does not reflect a final decision on the information under review. The letter did not state what the deficiencies are."[8]

99. On the Company's earnings call that day, Defendant Tabuteau acknowledged that "[a]lthough the [FDA] letter stated that the notification does not reflect a final decision on the information under review, this development may lead to a delay in the potential approval of AXS-05. We will keep you informed as we learn more."

100. The market reacted very negatively to this news because it meant that, at the very

[8] The FDA explains that post-marketing requirements and commitments are "studies and clinical trials that sponsors conduct after approval to gather additional information about a product's safety, efficacy, or optimal use." While these studies are not completed until after approval, they may be set out as part of the approval process.

least, there would be a substantial delay in the approval of AXS-05. For instance, Guggenheim Securities issued a report warning investors that "AXS-05 approval now in question after FDA letter noting 'deficiencies' in the NDA filing."

101. That day, on August 9, 2021, the Company's stock price fell by 46.5%, from a closing price of $51.16 per share the day before to a closing price of $27.37 that day.

102. Following this time, Defendants were on heightened notice that the FDA might not approve the Company's Applications because of CMC issues with the drug candidates. At the time, AXS-07 was the Company's only other product to have had an NDA submitted. Moreover, while the Company had the opportunity to fix the CMC issues with AXS-05 under its original NDA, the CMC issues with AXS-07 were even more serious because they led to the FDA issuing a CRL denying the drug's Application. Defendants should have been extra attuned to CMC problems following the CMC issues that the FDA raised with AXS-05.

103. On August 23, 2021, the Company updated investors, stating that the FDA "informed the Company in a teleconference on August 20, 2021, that its review of the new drug application (NDA) for AXS-05 for the treatment of major depressive disorder would not be completed by the PDUFA target action date of August 22, 2021. The FDA did not request additional information from the Company, and the review of the application is ongoing."

104. On November 8, 2021, during the Company's earnings call for the third quarter of 2021, Defendant Tabuteau disclosed that the FDA "recently informed us of two deficiencies related to analytical methods in the chemistry, manufacturing and control section of the NDA [for AXS-05], which must be addressed prior to the FDA taking action on the NDA."

105. CW 1 (who was a Senior Clinical Trial Manager at the Company from July 2019 to February 2022), noted other deficiencies that the FDA identified with AXS-05 due to a "poorly

written" testing protocol. The sloppy testing protocol did not clearly indicate to the clinical trial sites that patients who did not complete their data entry requests during clinical trial visits by at least 80 percent, were not eligible to participate in the study. Due to the lack of clarity, clinical testing sites allowed patients who did not meet this requirement to participate in the study. A clinical trial site for AXS-05, that was audited by the FDA, received a Form 483 from the agency in November 2021 for not excluding patients from the study who failed to meet this criteria.

106. A Form 483 "is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. . . . The FDA Form 483 notifies the company's management of objectionable conditions."[9]

107. The FDA ultimately approved AXS-05 on August 19, 2022. While the market reacted positively to this news, it came one year after AXS-05 initial PDUFA date of August 22, 2021. This significant delay left the market with substantial uncertainty during that time.

FALSE AND MISLEADING STATEMENTS

108. On December 30, 2019, the Company issued a press release reporting that AXS-07 had met its two regulatory co-primary endpoints in a Phase 3 trial called the MOMENTUM trial for the treatment of migraine. That press release stated that: "[t]he positive results on both co-primary endpoints along with the demonstration of component contribution support the filing of an NDA for AXS-07 in the acute treatment of migraine"; that "[b]ased on FDA feedback, Axsome believes that MOMENTUM will be the only efficacy trial required to support an NDA filing for AXS-07 for the acute treatment of migraine"; and that "Axsome plans to file the NDA in the

9 https://www.fda.gov/inspections-compliance-enforcement-and-criminalinvestigations/inspection-references/fda-form-483-frequently-asked-questions.

second half of 2020."

109. In that same December 30, 2019 press release, Defendant Tabuteau stated:

> "These data have potentially important implications for patient care based on the high rate of inadequate response to and patient dissatisfaction with current treatments. With these positive results, we look forward to filing an NDA for AXS-07 in the acute treatment of migraine in 2020."

110. On March 12, 2020, the Company issued a press release reporting the Company's fourth quarter and full year 2019 results, stating that "[t]he positive results from the MOMENTUM trial support an NDA filing for AXS-07 in the acute treatment of migraine, which is anticipated in the fourth quarter of 2020"; and that "[t]o support the planned NDA filing of AXS- 07 in the acute treatment of migraine, enrollment in a Phase 3 open-label, long-term safety extension study of AXS-07 is ongoing."

111. On that same date, the Company hosted a conference call with its stockholders to discuss the Company's fourth quarter and full year 2020 results. It was at that conference Defendant Tabuteau stated:

> The positive results from the MOMENTUM trial support an NDA filing for AXS-07 in the acute treatment of migraine and we remain on track to file this NDA in the second half of 2020. With . . . two planned NDA filings Axsome is on track to transition to commercial stage potentially as early as next year.

112. On March 12, 2020, the Company filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2019 (the "2019 10-K"). That filing provided generic representations concerning potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing, stating that "the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional . . . [CMC], or other data and information."

113. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), wherein Defendants Tabuteau and Pizzie certified that "[t]he [2019 10-K] fully complies with the requirements of Section 13(a) or 15(d) of the [Exchange Act], as amended[,]" and that "[t]he information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

114. On April 6, 2020, the Company issued a press release reporting that AXS-07 had met its co-primary endpoints in a second Phase 3 trial called the INTERCEPT trial for the treatment of migraine. Defendant Tabuteau stated:

> With INTERCEPT and the previously completed MOMENTUM Phase 3 trial in patients with a history of inadequate response to prior acute treatments, AXS-07 has now been evaluated in two positive well-controlled trials . . . . INTERCEPT strengthens our planned NDA for AXS-07 in the acute treatment of migraine, which remains on track to be submitted to the FDA in the fourth quarter.

115. On May 8, 2020, the Company issued a press release reporting the Company's first quarter 2020 results, stating:

> As we move towards the submission of two NDAs in the fourth quarter . . . one for AXS-07 in migraine, our commercial team is focused on launch-readiness activities to ensure successful commercial execution.
>
> * * *
>
> Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials. A Phase 3, open-label, long-term safety extension study of AXS-07 is ongoing to further support the NDA filing.

116. The same day, the Company hosted a conference call with its stockholders to discuss the Company's first quarter 2020 results. On that call, in response to an analyst question regarding whether there "[i]s . . . any new clinical data, including . . . CMC activities" for the Company's NDAs, Defendant Tabuteau stated:

> With regards to CMC activities, there are registration batches which are being manufactured now. A good thing for us is that we have been manufacturing our clinical trial supply at commercial scale and also at the same CMO that we're using for commercial production. So, there's no scale up that needs to be done.
>
> Now, with regards to manufacturing and any kind of science to it, there's always tweaks and experimentation, but I would say that there is no rate-limiting step and there is no extensive experimentation. This is simply manufacturing our registration batches for regulatory purposes.

117. On May 11, 2020, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2020 (the "1Q20 10-Q"). That filing provided generic representations concerning potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing, stating that "in connection with the [CMC] data necessary for our NDA filings, we will need to conduct stability studies and provide stability data to establish appropriate retest or expiration dating period"; and that "[d]uring the course of review, the FDA may also request or require additional CMC, or other data and information, and the development and provision of these data and information may be time consuming and expensive."

118. Appended as exhibits to the 1Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 113 signed by Defendants Tabuteau and Pizzie.

119. On August 10, 2020, the Company issued a press release reporting the Company's second quarter 2020 results, stating:

> Axsome remains on track to submit an NDA for AXS-07 in the acute treatment of migraine to the FDA in the fourth quarter of 2020. The NDA is supported by positive efficacy results from the MOMENTUM and INTERCEPT trials. Enrollment has been completed in the MOVEMENT (Multimechanistic Treatment Overtime of Migraine Symptoms) Phase 3 open-label, long-term safety trial to support the planned NDA filing of AXS-07 in the acute treatment of migraine. More than 700 patients have been enrolled, approximately 450 of whom have been treated with AXS-07 for at least 6 months to date.

120. That same day, the Company hosted a conference call with its stockholders to

discuss the Company's second quarter 2020 results. It was at this conference Defendant Tabuteau stated:

> Over the past several months, we continued to advance our . . . AXS-07 product candidate[] towards NDA submission[] in . . . migraine[.]
>
> * * *
>
> [W]e remain on track to submit the NDA for AXS-07 for the acute treatment of migraine in the fourth quarter. To that end, we have completed enrollment in the Phase 3 open-label safety extension trial of AXS-07 in migraine, which we call the MOVEMENT study to support the planned NDA filing. As we move towards the filing of our NDA[] in the fourth quarter . . . for AXS-07, our commercial team is focused on launch-readiness activities to ensure successful commercial execution.

121. Also, on this same day, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2020 (the "2Q20 10-Q"). That filing contained the same statements referenced in ¶ 112, *supra*, providing generic representations concerning potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

122. Appended as exhibits to the 2Q20 10-Q were the same SOX certifications as referenced in ¶ 113 signed by Defendants Tabuteau and Pizzie.

123. The statements referenced above were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company's CMC practices were deficient with respect to AXS-07 and its manufacturing process; (ii) as a result, the Company was unlikely to submit the AXS-07 NDA on its initially represented timeline; (iii) the foregoing CMC issues remained unresolved at the time that the FDA reviewed the AXS-07 NDA; (iv) accordingly, the FDA was unlikely to approve the AXS-07 NDA; (v) as a result of all the

foregoing, the Company had overstated AXS-07's regulatory and commercial prospects; and (vi) as a result, the Company's public statements were materially false and misleading at all relevant times.

THE TRUTH EMERGES

124. On November 5, 2020, the Company issued a press release reporting the Company's third quarter 2020 results. That press release disclosed that "Axsome now plans to submit the [AXS-07] NDA to the FDA in the first quarter of 2021, versus previous guidance of the fourth quarter of 2020, to allow for inclusion of supplemental manufacturing information to ensure a robust submission package."

125. On this news, the Company's stock price fell $5.22 per share, or 6.99%, to close at $69.51 per share on November 5, 2020. Despite this decline in the Company's stock price, the Company's stock continued to trade at artificially inflated prices because of Defendants' continued misrepresentations and omissions regarding CMC issues with the AXS-07 NDA.

126. For instance, the same November 5, 2020 press release stated that "[p]resubmission activities for the Company's NDA for AXS-07 in the acute treatment of migraine are progressing with major NDA-related items on track for completion by year-end."

127. The same November 5, 2020 press release also quoted Defendant Tabuteau, who stated, in relevant part, that "[o]ver the past several months, we continued to advance our . . . AXS-07 product candidate[] towards NDA submission[] in . . . migraine, and intensified our commercial launch readiness activities," and that "[w]e anticipate an active next few months as we complete our NDA submission[] for . . . AXS-07[.]"

128. That same day, the Company hosted a conference call with its stockholders to discuss the Company's third quarter 2020 results. In his prepared remarks, Defendant Tabuteau

stated again that the Company was taking steps to ensure a robust AXS-07 NDA submission with respect to the drug's manufacturing, stating:

> Switching now to our migraine program with AXS-07. The major MDA related items are on track for completion by year end. We now plan to submit the NDA in the first quarter of 2021 versus previous guidance of the fourth quarter of 2020 in order to allow for inclusion of supplemental manufacturing information. We believe that this approach will enhance the robustness of our submission.

129. On the same call, in response to multiple analyst questions concerning the additional manufacturing information that the Company submitted to the FDA for the AXS-07 NDA, Defendants Tabuteau and Jacobson assured investors that the additional information was just to ensure a robust submission and did not reflect any manufacturing issues. For instance, an exchange with one analyst read, in relevant part:

> **[SVB Leerink Analyst]**
>
> And then the second issue was the – for [AXS-]07. You talked about the NDA in the first quarter, including extra manufacturing information. Can you give us kind of the same sense of confidence that, as - you know, my first question, with respect to what's going on here, may give us a little bit more color and how much we're on top of it. And it's definitely going to be not any more delayed than that?
>
> **[Defendant] Tabuteau**
>
> * * *
>
> So with regards to AXS-07, this is a little bit of a different situation. Here, this is a situation whereby by the end of the year, we will have completed all the major activities, which are needed to file our NDA. And we're on track to do that. And because of the unique manufacturing, behind the mosaic technology, we want to make sure that we have as robust as possible of a submission package.
>
> So we continue to generate data. And the question is, how much do you include. And since, you know, we will be having some data in the early part of the year, we'd love to be able to include that in the package. But to provide some additional color on that, I'm going to turn it over to [Defendant] Jacobson.
>
> **[Defendant] Jacobson**

> Good morning, Marc. So just want to be clear, this is not the result of the manufacturing or stability issue or anything like that. Exactly as [Defendant Tabuteau] said, that we will have data available, that we think would add to the submission given us a novel delivery technology. And so that will just allow us to make the package as robust as possible.

130. In response to a similar question from another analyst, Defendant Tabuteau again downplayed issues with respect to AXS-07's manufacturing:

> **Unidentified Analyst**
>
> Thank you for taking our questions. This is Miguel on the line for Joon. Could you provide more specifics on what manufacturing data related to the mosaic platform will be added for AXS-07?
>
> * * *
>
> **[Defendant] Tabuteau**
>
> Great. So with regards to the additional manufacturing information, this is a standard information when you manufacture additional batches. So we continue to manufacture additional batches of drugs. And while we already have very longterm stability data on other batches, we think that because of the unique nature of the delivery technology, this can only help to make the submission robust and assure that there are no hiccups during review.

131. Also, on November 5, 2020, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2020 (the "3Q20 10-Q"). That filing contained the same statements referenced in ¶ 112, *supra*, providing generic representations concerning potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

132. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX certifications as referenced in ¶ 113, signed by Defendants Tabuteau and Pizzie.

133. On March 1, 2021, the Company issued a press release reporting the Company's fourth quarter and full year 2020 results. Defendant Tabuteau stated that the Company "had

successful pre-NDA meetings with the FDA . . . for AXS 07 in migraine" and "are nearing submission of the NDA for AXS-07 in the acute treatment of migraine, which is expected early in the second quarter." Similarly, Defendant Tabuteau assured investors that "[o]ur focus for the remainder of the year will be on the regulatory activities surrounding these NDAs, [and] launch readiness to ensure a successful transition to commercialization[.]"

134. That same day, the Company hosted a conference call with its stockholders to discuss the Company's fourth quarter and full year 2020 results. Defendant Tabuteau reiterated that Defendants were "completing compilation of the [AXS-07] NDA which we expect to submit to the FDA early in the second quarter."

135. On the same call, Defendant Tabuteau stated: "With regard [AXS-]07 and the NDA filing the team remains on track to complete the filing by the end of the quarter. However, we are waiting on one vendor report which will slip into very beginning of the second quarter and that's the reason[.]"

136. Also, on March 1, 2021, the Company filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2020 (the "2020 10-K"). That filing contained the same statements referenced in ¶ 112, *supra*, providing generic representations concerning potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

137. Appended as exhibits to the 2020 10-K were substantively the same SOX certifications as referenced in ¶ 113, *supra*, signed by Defendants Tabuteau and Pizzie.

138. On May 10, 2021, the Company issued a press release concerning its first quarter 2021 results. That press release stated that "Axsome is compiling the NDA for AXS-07 for the

acute treatment of migraine, which is on track for submission to the FDA in the second quarter of 2021."

139. That same day, the Company hosted a conference call with its stockholders to discuss the Company's first quarter 2021 results. In response to a question regarding "what the gating factors are in terms of getting th[e AXS-07 NDA] submission into the FDA" given that the Company had pushed back its regulatory timeline multiple times, Defendant O'Gorman stated: "With regards to AXS-07, we're very much on track to file the NDA this quarter, as we've previously stated, and there really isn't any update there. The team is working diligently to make sure that we have a timely, but also a quality filing."

140. Also on May 10, 2021, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended March 31, 2021 (the "1Q21 10-Q"). That filing contained substantively the same statements referenced in ¶ 112, *supra*, providing generic representations concerning potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the anticipated AXS-07 NDA filing.

141. Appended as exhibits to the 1Q21 10-Q were substantively the same SOX certifications as referenced in ¶ 113, signed by Defendants Tabuteau and Pizzie.

142. On August 9, 2021, the Company issued a press release reporting the Company's second quarter 2021 results. That press release quoted Defendant Tabuteau, who noted that although the FDA had identified deficiencies with an NDA for the Company's AXS-05 product candidate, "[o]ur other programs continue to advance" and "[w]e successfully filed our NDA for AXS-07 for the acute treatment of migraine in the second quarter[.]"

143. That same day, the Company hosted a conference call with its stockholders to

discuss the Company's second quarter 2021 results. In response to an analyst question regarding whether AXS-07 is manufactured at the same facility as AXS-05, Defendant Jacobson stated:

> So for the manufacturing process for AXS-07, that actually is a bit more complicated and there are two facilities that we utilized for the manufacturer of the drug product. The drug -- the API's are also available under open DMF too in the U.S. And of the two facilities that we used for drug product manufacturing, one of them is the same that we used for AXS-05.

144. Also on August 9, 2021, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended June 30, 2021 (the "2Q21 10-Q"). That filing contained substantively the same statements referenced in ¶ 112, *supra*, providing generic representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the AXS-07 NDA.

145. Appended as exhibits to the 2Q21 10-Q were substantively the same SOX certifications as referenced in ¶ 113, signed by Defendants Tabuteau and Pizzie.

146. On September 14, 2021, the Company issued a press release reporting that the FDA had accepted the AXS-07 NDA, stating:

> [T]he [FDA] has accepted for filing the Company's [NDA] for AXS-07 for the acute treatment of migraine, and has set a [PDUFA] target action date of April 30, 2022 for the NDA. AXS-07 (MoSEIC™ meloxicam-rizatriptan) is a novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for migraine.
>
> "The FDA's acceptance of the NDA for AXS-07 is an important milestone for Axsome as it brings us closer to potentially making this multi-mechanistic treatment available to migraine patients in need," said [Defendant] Tabuteau, MD, Chief Executive Officer of Axsome. "We look forward to continued interactions with the FDA during the review process."
>
> The NDA is supported by results from two Phase 3 randomized, double-blind, controlled trials of AXS-07 in the acute treatment of migraine, the MOMENTUM and INTERCEPT trials, which demonstrated statistically significant elimination of migraine pain with AXS-07 compared to placebo and active controls.

147. On November 8, 2021, the Company issued a press release reporting the Company's third quarter 2021 results. Defendant Tabuteau stated:

> Over the past several months we have continued to advance our differentiated latestage CNS product candidates aimed at meaningfully improving the lives of patients . . . . [T]he NDA for AXS-07 in migraine was accepted, positioning Axsome to potentially commercialize two new treatments in the near to intermediate term for patients living with . . . serious CNS disorders[.]

148. The same November 8, 2021 press release also advised stockholders that "[t]he FDA notified the Company that, due to COVID-19 pandemic-related travel restrictions, they may be unable to complete a required inspection of a contract manufacturing facility [for the AXS-07 NDA] . . . prior to the PDUFA date[.]"

149. That same day, the Company hosted a conference call with its stockholders to discuss its third quarter 2021 results. On that call, in response to an analyst question regarding the FDA's delayed inspection of the contract manufacturing facility for the AXS-07 NDA, Defendants Tabuteau and Laliberte downplayed issues with manufacturing on the drug's regulatory timeline:

> **[SVB Leerink Analyst]**
>
> Just one quick question on the migraine, can you just help us understand, did you say that one of the two manufacturing sites might not be able to be signed off on by the PDUFA date? So you're implying that one could be and is one enough? Do you both have to be filed? I was a little confused by your comment. Thank you.
>
> **[Defendant] Tabuteau**
>
> Yes. So it's – I'll turn it over to [Defendant Laliberte], who will respond to that. But I think it's pretty straightforward in terms of what the FDA is trying to give a sense on there.
>
> **[Defendant] Laliberte**
>
> Thanks for that question. So there are obviously multiple manufacturing sites involved in the process for AXS-07. The FDA notified us that one specific manufacturing location that is based in the United States is required to have an inspection prior to them, as part of the review process. And then they did notify us that because of COVID-related restrictions, that may be in jeopardy of happening

> before the PDUFA date. So it's just this one manufacturer based in the United States that they specifically notified us of in their communication.

150. Also on November 8, 2021, the Company filed a quarterly report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarter ended September 30, 2021 (the "3Q21 10-Q"). That filing contained substantively the same statements referenced in ¶ 112, *supra*, providing generic representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the AXS-07 NDA.

151. Appended as exhibits to the 3Q21 10-Q were substantively the same SOX certifications as referenced in ¶ 113, signed by Defendants Tabuteau and Pizzie.

152. On March 1, 2022, Axsome issued a press release reporting the Company's fourth quarter and full year 2021 results. That press release stated, in relevant part:

> Axsome's NDA for AXS-07 for the acute treatment of migraine is currently under review by the FDA with a PDUFA target action date for the NDA of April 30, 2022. The FDA previously notified the Company that, due to COVID-19 pandemic related travel restrictions, they may be unable to complete a required inspection of a contract manufacturing facility, located in the United States, prior to the PDUFA date. Axsome has since been informed by the FDA that it does not anticipate any issues with completing this facility inspection prior to the AXS-07 PDUFA date.

153. The same March 1, 2022 press release also quoted Defendant Tabuteau, who represented that "2021 was a year of continued progress which has put us in a position to potentially launch two new investigational medicines for patients living with depression and migraine," including "the April 30 PDUFA date for our NDA for AXS-07 in the acute treatment of migraine [that] is approaching."

154. That same day, the Company filed an annual report on Form 10-K with the SEC, reporting the Company's financial and operating results for the quarter and year ended December 31, 2021 (the "2021 10-K"). That filing contained substantively the same statements referenced

in ¶ 112, *supra*, providing generic representations regarding potential CMC issues that could materialize for any given NDA filing, without addressing CMC issues specific to the AXS-07 NDA.

155. Appended as exhibits to the 2021 10-K were substantively the same SOX certifications as referenced in ¶ 113, signed by Defendants Tabuteau and Pizzie.

156. The statements referenced above were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company's CMC practices were deficient with respect to AXS-07 and its manufacturing process; (ii) the foregoing CMC issues remained unresolved at the time that the FDA reviewed the AXS-07 NDA; (iii) accordingly, the FDA was unlikely to approve the AXS-07 NDA; (iv) as a result of all the foregoing, the Company had overstated AXS-07's regulatory and commercial prospects; and (v) as a result, the Company's public statements were materially false and misleading at all relevant times.

THE TRUTH FULLY EMERGES

157. On April 25, 2022, the Company filed a current report on Form 8-K with the SEC, stating:

> On April 22, 2022, Axsome . . . was informed by the [FDA] that [CMC] issues identified during the FDA's review of the Company's [NDA] for its AXS-07 product candidate for the acute treatment of migraine are unresolved. Based upon the time remaining in the NDA review cycle, the Company expects to receive a [CRL] with respect to this NDA on or about the [PDUFA] target action date of April 30, 2022.

158. On this news, the Company's stock price fell $8.60 per share, or 21.99%, to close at $30.50 per share on April 25, 2022.

159. On May 2, 2022, the Company issued a press release reporting that it received a

CRL from the FDA regarding the AXS-07 NDA for the acute treatment of migraine. That press release stated:

> [T]he Company has received a [CRL] from the [FDA] regarding its [NDA] for AXS-07 for the acute treatment of migraine. The CRL did not identify or raise any concerns about the clinical efficacy or safety data in the NDA, and the FDA did not request any new clinical trials to support the approval of AXS-07.
>
> The principal reasons given in the CRL relate to [CMC] considerations. The CRL identified the need for additional CMC data pertaining to the drug product and manufacturing process. Axsome believes that the issues raised in the CRL are addressable and intends to provide potential timing for a resubmission following consultation with the FDA.

DAMAGES TO THE COMPANY

160. As a direct and proximate result of the Individual Defendants' conduct, the Company has been seriously harmed and will continue to be. Such harm includes, but is not limited to:

(a) Any funds paid to settle the Securities Class Action; and

(b) Costs incurred from compensation and benefits paid to the defendants who have breached their duties to the Company.

161. In addition, the Company's business, goodwill, and reputation with its business partners, regulators, and shareholders have been gravely impaired. The Company still has not fully admitted the nature of its false statements and the true condition of its business. The credibility and motives of management are now in serious doubt.

162. The actions complained of herein have irreparably damaged the Company's corporate image and goodwill. For at least the foreseeable future, the Company will suffer from what is known as the "liar's discount," a term applied to the stocks of companies who have been implicated in illegal behavior and have misled the investing public, such that the Company's ability to raise equity capital or debt on favorable terms in the future is now impaired.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

163. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of Defendants' violations of Sections 10(b) and 21D of the Exchange Act, and their breaches of fiduciary duties and other wrongful conduct as alleged herein and that occurred during the Relevant Period.

164. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

165. Plaintiff is a current owner of the Company stock and has been an owner of Company stock during the Relevant Period. Plaintiff understands his obligation to hold stock throughout the duration of this action and are prepared to do so.

166. Because of the facts set forth herein, Plaintiff has not made a demand on the Board of the Company to institute this action against the Director Defendants. Such demand would be a futile and useless act because the Board is incapable of making an independent and disinterested decision to institute and vigorously prosecute this action. A pre-suit demand on the Board is futile and, therefore, excused.

167. At the time this suit was filed, the Board was comprised of four (4) members -- Tabuteau, Jeffs, Coleman, and Saad. Thus, Plaintiff is required to show that a majority of Defendants, *i.e.*, two (2), could not exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action.

168. The Director Defendants face a substantial likelihood of liability in this action because they caused the Company to issue false and misleading statements concerning the

information described herein. Because of their advisory, executive, managerial, and directorial positions with the Company, the Director Defendants had knowledge of material non-public information regarding the Company and were directly involved in the operations of the Company at the highest levels.

169. The Director Defendants either knew or should have known of the false and misleading statements that were issued on the Company's behalf and took no steps in a good faith effort to prevent or remedy that situation.

170. The Director Defendants (or at the very least a majority of them) cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. For the reasons that follow, and for reasons detailed elsewhere in this Complaint, Plaintiff did not make (and was excused from making) a pre-filing demand on the Board to initiate this action because making a demand would have been a futile and useless act.

171. Each of the Director Defendants approved and/or permitted the wrongs alleged herein to have occurred and participated in efforts to conceal or disguise those wrongs from the Company's stockholders or recklessly and/or with gross negligence disregarded the wrongs complained of herein and are therefore not disinterested parties.

172. Each of the Director Defendants authorized and/or permitted the false statements to be disseminated directly to the public and made available and distributed to shareholders, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein, and thus, could not fairly and fully prosecute such a suit even if they instituted it.

173. Additionally, each of the Director Defendants received payments, benefits, stock options, and other emoluments by virtue of their membership on the Board and their control of the

Company.

ADDITIONAL INFORMATION REGARDING DEMAND FUTILITY

Defendants Jeffs, Coleman and Saad

174. Defendants Jeffs, Coleman and Saad served as members of the Audit Committee at relevant times. As such they are responsible for the integrity of the Company's disclosures. The AXS-07 NDA presented a critical opportunity for the Company's transition to a commercial company. In their capacities as Audit Committee members, Defendants Jeffs, Coleman and Saad reviewed and approved the materially misleading statements and allowed them to be disseminated in the Company's SEC filings and other disclosures. Thus, Defendants Jeffs, Coleman and Saad breached their fiduciary duties and are not disinterested, and demand is excused as to them.

Defendant Tabuteau

175. Defendant Tabuteau is the CEO of the Company. Defendant Tabuteau is also a director of the Company.

176. Defendant Tabuteau is not disinterested or independent, and therefore, is incapable of considering demand because Tabuteau (as CEO) is an employee of the Company who derived substantially all of his income from his employment with the Company, making him not independent. As such, Tabuteau cannot independently consider any demand to sue himself for breaching his fiduciary duties to the Company, because that would expose him to liability and threaten his livelihood.

177. This lack of independence and financial benefits received by Defendant Tabuteau renders him incapable of impartially considering a demand to commence and vigorously prosecute this action.

178. Defendant Tabuteau is also a defendant in the Securities Class Action.

COUNT I

(Against Defendants Tabuteau, Pizzie, O'Gorman, and Laliberte For Violations of Sections 10(b) And 21D Of The Exchange Act)

179. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

180. The Company, along with Defendants Tabuteau, Pizzie, O'Gorman, and Laliberte are named as defendants in the Securities Class Action, which assert claims under the federal securities laws for violations of Sections 10(b) and 20(a) of the Exchange Act, and SEC Rule 10b-5 promulgated thereunder. If and when the Company is found liable in the Securities Class Action for these violations of law, the Company's liability will be in whole or in part due to Defendants Tabuteau, Pizzie, O'Gorman, and Laliberte's willful and/or reckless violations of their obligations as officers and directors of the Company.

181. Through their positions of control and authority as officers of the Company, Defendants Tabuteau, Pizzie, O'Gorman, and Laliberte were able to and did, directly and/or indirectly, exercise control over the business and corporate affairs of the Company, including the wrongful acts described in the Securities Class Action and herein.

COUNT II

(Against The Director Defendants For Breach of Fiduciary Duty)

182. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

183. The Director Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Director Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

184. The Director Defendants violated and breached their fiduciary duties of care,

loyalty, reasonable inquiry, and good faith.

185. The Director Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Director Defendants breached their fiduciary duties of loyalty and good faith by allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

186. As a direct and proximate result of the Director Defendants' failure to perform their fiduciary obligations, the Company has sustained significant damages. As a result of the misconduct alleged herein, the Director Defendants are liable to the Company.

187. As a direct and proximate result of the Director Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs associated with defending and/or settling securities lawsuits and governmental investigations, severe damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.

COUNT III

(Against Defendants For Waste of Corporate Assets)

188. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

189. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the Relevant Period. It resulted in continuous, connected, and ongoing harm to the Company.

190. As a result of the misconduct described above, the Director Defendants wasted corporate assets by, *inter alia*: (a) paying excessive compensation, bonuses, and termination payments to certain of its executive officers; (b) awarding self-interested stock options to certain officers and directors; and (c) incurring potentially millions of dollars of legal liability and/or legal costs to defend and/or settle actions addressing Defendants' unlawful actions.

191. As a result of the waste of corporate assets, the Director Defendants are liable to the Company.

192. Plaintiff, on behalf of the Company, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(A) Declaring that Plaintiff may maintain this action on behalf of the Company and that Plaintiff is an adequate representative of the Company;

(B) Finding Defendants liable for breaching their fiduciary duties owed to the Company;

(C) Directing Defendants to take all necessary actions to reform and improve the Company's corporate governance, risk management, and internal operating procedures to comply with applicable laws and to protect the Company and its stockholders from a repeat of the rampant wrongful conduct described herein;

(D) Awarding damages to the Company for the harm the Company suffered as a result of the Defendants' wrongful conduct;

(E) Awarding damages to the Company for Defendants Tabuteau, Pizzie, O'Gorman, and Laliberte's violations of Sections 10(b) and 21D of the Exchange Act;

(F) Awarding Plaintiff the costs and disbursements of this action, including attorneys', accountants', and experts' fees; and

(G) Awarding such other and further relief as is just and equitable.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all issues so triable.

Dated: January 27, 2023

GAINEY McKENNA & EGLESTON

By: */s/ Gregory M. Egleston*
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VERIFICATION

I, KYLE GUTERBA, declare that I have reviewed the Verified Shareholder Derivative Complaint ("Complaint") prepared on behalf of Axsome Therapeutics, Inc. ("Axsome") and authorize its filing. I have reviewed the allegations made in the Complaint, and to those allegations of which I have personal knowledge, I believe those allegations to be true. As to those allegations of which I do not have personal knowledge, I rely on my counsel and their investigation and for that reason believe them to be true. I further declare that I am a current holder, and have been a holder, of Axsome as set forth in the Complaint.

Kyle Guterba

KYLE GUTERBA